Registration Form

Assessment of the Allergenic Potential of Genetically Modified Foods
December 10-12, 2001
(Open to the public, limited only by space available)
Sheraton Chapel Hill, Chapel Hill, NC

(Type or print clearly)

Last Name _____ First Name _____ Middle Initial _____

Institution _____ Department _____

Address _____

City _____ State _____ Zip Code _____

Office Phone _____ Fax Number _____ E-mail Address _____

Registration Fee: $65.00

Make checks payable to:
Allergenic Potential of Genetically Modified Foods

Mail your registration, with check or money order, no later than November 30, 2001, to:
NTP Liaison Office
NTP/NIEHS
P.O. Box 12233, MD: A3-01
Research Triangle Park, NC 27709
(919) 541-0530

Breakout Groups: (mark first and second choice)	1st	2nd
1. Use of Human Clinical Data for Risk Assessment	___	___
2. Animal Models to Assess Food Allergy	___	___
3. Biomarkers of Exposure and Effect	___	___
4. Sensitive Populations	___	___
5. Models of Dose Response	___	___
6. Post-Market Surveillance	___	___

DEPARTMENT OF
HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health
National Institute of
Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, NC 27709

Official Business

Registration Package

Assessment of the Allergenic Potential of Genetically Modified Foods

December 10-12, 2001

Sheraton Chapel Hill
Chapel Hill, NC

Sponsored by the

Office of Research and Development,
U.S. Environmental Protection Agency

National Toxicology Program,
Department of Health and Human Services

National Institute of Environmental Health Sciences,
National Institutes of Health

Office of Rare Diseases,
National Institutes of Health

Center for Food Safety and Nutrition,
U.S. Food and Drug Administration

Organized by the

National Institute of Environmental Health Sciences
National Toxicology Program
Research Triangle Park, NC

NTP

NIEHS

Purpose

There is growing concern among the general public and the scientific community regarding the potential toxicity of genetically modified (GM) foods. Of specific interest is the ability of GM proteins to elicit potentially harmful immunologic responses including hypersensitivity and/or autoimmunity. The lack of information on the potential toxicity of these products has created a considerable backlash against the producers and users of these crops. This meeting will gather experts in food allergy, GM crops and the regulatory aspects of these products, along with bench scientists and clinicians, to examine the current state of knowledge in the area, identify the critical issues and research needs regarding these materials and develop testing strategies to examine the allergenicity of these compounds.

Tentative Agenda

Registration and continental breakfast will be each day from 7:30 - 8:30 a.m. Attendees are responsible for their own lunch and dinner.

Monday, December 10, 2001

8:30 - 8:45 a.m.	Welcome
8:45 - 9:40 a.m.	Introduction: What are the issues? Dr. Dean Metcalfe NCFST Conference Conclusions, November 2000 Dr. Steven Gendel

Session I – Clinical Aspects and Clinical Investigation of Food Allergy

9:40 - 10:10 a.m.	Clinical Spectrum of Food Allergy Dr. Hugh Sampson
10:10 - 10:30 a.m.	Break
10:30 - 11:00 a.m.	Clinical Assessment of Food Allergy to Novel Proteins Dr. Sam Lehrer
11:00 - 11:30 a.m.	Contribution of Inhalation Allergenicity - Occupational / Rural Exposures Dr. Leonard Bernstein
11:30 - 12:00 p.m.	Serum Screening and Challenges for Allergenicity Safety Assessment Dr. Robert Hamilton
12:00 - 1:00 p.m.	Lunch
1:00 - 1:40 p.m.	Post-Marketing Surveillance Dr. Carol Rubin

Session II – Toxicological Evaluation of Novel Proteins

1:40 - 2:40 p.m.	Assessment of Protein Structure, Sequence Homology and Stability Dr. Tong-Jen Fu Dr. Gary Bannon
2:40 - 3:00 p.m.	Break

Session III – Regulatory Considerations

3:00 - 4:15 p.m.	Panel Discussion This session will consist of short presentations from regulatory and industry scientists followed by a panel discussion. Panelists will consider what studies (data) are most useful in assessing the safety of exposure to potentially allergenic substances and what are the biggest uncertainties. Speaker/Panelist Dr. Kathleen Jones (FDA) Dr. John Kough (EPA) Dr. Kathy Sarlo (Proctor and Gamble) Dr. Val Giddings (Biosys) Dr. James Astwood (Monsanto)

Session IV – Risk Communication

4:15 - 5:00 p.m.	Biotechnology and How The Public Perceives It Dr. Thomas Hoban Dr. Rebecca Goldburg
5:00 p.m.	Open Discussion

Tuesday, December 11, 2001

Session V – Toxicological Methods of Safety Assessment

8:30 - 8:40 a.m.	Overview
8:40 - 9:15 a.m.	Oral and Intraperitoneal Exposure of Brown Norway Rats Dr. Andre Penninks
9:15 - 9:50 a.m.	Oral and Systemic Exposure of BALB/c Mice Dr. Ian Kimber
9:50 - 10:25 a.m.	Assessment of Allergenicity Using Swine Models Dr. Ricki Helm
10:25 - 10:45 a.m.	Break
10:45 - 11:20 a.m.	Assessment of Allergenicity in Dogs I Dr. Robert Buchanan
11:20 - 12:00 p.m.	Assessment of Allergenicity in Dogs II Dr. Bruce Hammerberg
12: 00 - 1:00 p.m.	Lunch
1:00 - 1:15 p.m.	Charge to Breakout Groups

Session VI – Breakout Group Meetings

1:15 - 2:45 p.m.	Address Questions, Research Needs and Areas of Particular Focus
2:45 - 3:00 p.m.	Break
3:00 - 3:30 p.m.	Observer Question and Discussion Session
5:00 p.m.	Adjourn

Wednesday, December 12, 2001

Session VII – Breakout Group Presentations

8:30 - 10:30 a.m.	Presentations
10:30 - 10:50 a.m.	Break
10:50 - 11:15 a.m.	Presentations Continued
11:15 – 12:30 p.m.	Meeting Summary and Discussion Consensus Building and Agreement on the Way Forward
12:30 p.m.	Adjourn

Breakout Groups

The afternoon of the 11th will be devoted to breakout sessions. Breakout group reports will be presented the morning of the 12th. Meeting participants will divide into breakout groups that will address questions and evaluate research needs in the areas of:

1. Use of Human Clinical Data for Risk Assessment
2. Animal Models to Assess Food Allergy
3. Biomarkers of Exposure and Effect
4. Sensitive Populations
5. Models of Dose Response
6. Post-Market Surveillance

We anticipate that each breakout group will consist of 8-10 individuals with varied expertise. On the final day of the meeting, each breakout group will report on their discussions of the state of the science, the research gaps in the specific area, and approaches to address these gaps.

In addition to the speakers and invited participants, interested scientists and the public are invited to attend the workshop as observers. The number of observers will be limited only by the available space. An open discussion session is scheduled each day to provide an opportunity for observers to contribute to the scientific discussion.

Accommodations

Hotel reservations can be made directly with the Sheraton Chapel Hill, 919-968-4900. A block of rooms is being held through Friday, November 23, 2001. The group rate is $80.00 per night, excluding taxes. Identify that you will be attending the NIEHS meeting.

For Registration Information, Contact Ms. Angie Sanders:
sanders5@niehs.nih.gov; 919-541-0530 (telephone); 919-541-0295 (fax)

For Scientific Information, Contact Dr. Dori Germolec:
germolec@niehs.nih.gov; 919-541-3230 (telephone); 919-541-0870 (fax)

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